§ 803.10 Generally, what are the reporting requirements that apply to me?

(a) If you are a device user facility, you must submit reports (described in subpart C of this part), as follows:

(1) Submit reports of individual adverse events no later than 10 work days after the day that you become aware of a reportable event:

(i) Submit reports of device-related deaths to us and to the manufacturer, if known, or

(ii) Submit reports of device-related serious injuries to the manufacturers or, if the manufacturer is unknown, submit reports to us.

(2) Submit annual reports (described in § 803.33) to us.

(b) If you are an importer, you must submit reports (described in subpart D of this part), as follows:

(1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable event:

(i) Submit reports of device-related deaths or serious injuries to us and to the manufacturer or

(ii) Submit reports of device-related malfunctions to the manufacturer.

(2) [Reserved]

(c) If you are a manufacturer, you must submit reports (described in subpart E of this part) to us, as follows:

(1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable death, serious injury, or malfunction.

(2) Submit reports of individual adverse events no later than 5 work days after the day that you become aware of:

(i) A reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health or

(ii) A reportable event for which we made a written request.

(3) Submit supplemental reports if you obtain information that you did not submit in an initial report.

§ 803.11 What form should I use to submit reports of individual adverse events and where do I obtain these forms?

(a) If you are a manufacturer or importer, you must submit reports of individual adverse events to FDA in an electronic format in accordance with § 803.12(a) and § 803.20, unless granted an exemption under § 803.19.

(b) Importer reports submitted to device manufacturers may be in paper format or an electronic format that includes all required data fields to ensure that the manufacturer has all required information.

(c) If you are a user facility, you must submit reports of individual adverse events in accordance with § 803.12(b) and § 803.20.

(d) Form FDA 3500A is available on the Internet at *http://www.fda.gov/medwatch/getforms.htm* or from Division of International and Consumer Education, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4621, Silver Spring, MD 20993–0002, by email: *DICE@fda.hhs.gov*, FAX: 301–847–8149, or telephone: 800–638–2041.

[79 FR 8846, Feb. 14, 2014, as amended at 80 FR 10587, Feb. 27, 2015]

§ 803.12 How do I submit initial and supplemental or followup reports?

(a) Manufacturers and importers must submit initial and supplemental or followup reports to FDA in an electronic format that FDA can process, review, and archive.

(b) User facilities that submit their reports and additional information to FDA electronically must use an electronic format that FDA can process, review, and archive. User facilities that submit their reports to FDA on paper must submit any written report or additional information required under this part to FDA, CDRH, Medical Device Reporting, P.O. Box 3002, Rockville, MD 20847–3002, using Form FDA 3500A. Each report must be identified (e.g., ''User Facility Report'' or ''Annual Report'').

(c) If you are confronted with a public health emergency, this can be

brought to FDA's attention by contacting FDA's Office of Crisis Management, Emergency Operations Center by telephone, 24-hours a day, at 301–796–8240 or toll free at 866–300–4374, followed by the submission of an email to: *emergency.operations@fda.hhs.gov*.

NOTE: This action does not satisfy your obligation to report under part 803.

(d) You may submit a voluntary telephone report to the MedWatch office at 800–FDA–1088. You may also obtain information regarding voluntary reporting from the MedWatch office at 800–FDA–1088. You may also find the voluntary Form FDA 3500 and instructions to complete it at: *http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm*.

§ 803.13 Do I need to submit reports in English?

Yes. You must submit all reports required by this part in English.

§ 803.15 How will I know if you require more information about my medical device report?

(a) We will notify you in writing if we require additional information and will tell you what information we need. We will require additional information if we determine that protection of the public health requires additional or clarifying information for medical device reports submitted to us and in cases when the additional information is beyond the scope of FDA reporting forms or is not readily accessible to us.

(b) In any request under this section, we will state the reason or purpose for the information request, specify the due date for submitting the information, and clearly identify the reported event(s) related to our request. If we verbally request additional information, we will confirm the request in writing.

§ 803.16 When I submit a report, does the information in my report constitute an admission that the device caused or contributed to the reportable event?

No. A report or other information submitted by you, and our release of that report or information, is not necessarily an admission that the device, or you or your employees, caused or contributed to the reportable event. You do not have to admit and may deny that the report or information submitted under this part constitutes an admission that the device, you, or your employees, caused or contributed to a reportable event.

§ 803.17 What are the requirements for developing, maintaining, and implementing written MDR procedures that apply to me?

If you are a user facility, importer, or manufacturer, you must develop, maintain, and implement written MDR procedures for the following:

(a) Internal systems that provide for:

(1) Timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements;

(2) A standardized review process or procedure for determining when an event meets the criteria for reporting under this part; and

(3) Timely transmission of complete medical device reports to manufacturers or to us, or to both if required.

(b) Documentation and recordkeeping requirements for:

(1) Information that was evaluated to determine if an event was reportable;

(2) All medical device reports and information submitted to manufacturers and/or us;

(3) Any information that was evaluated for the purpose of preparing the submission of annual reports; and

(4) Systems that ensure access to information that facilitates timely followup and inspection by us.

§ 803.18 What are the requirements for establishing and maintaining MDR files or records that apply to me?

(a) If you are a user facility, importer, or manufacturer, you must establish and maintain MDR event files. You must clearly identify all MDR event files and maintain them to facilitate timely access.

(b)(1) For purposes of this part, ''MDR event files'' are written or electronic files maintained by user facilities, importers, and manufacturers. MDR event files may incorporate references to other information (e.g., medical records, patient files, engineering reports), in lieu of copying and maintaining duplicates in this file. Your MDR event files must contain: